solution containing 3,200 micrograms of erythromycin per milliliter is not less than 7.5 and not more than 10.0. The erythromycin used conforms to the requirements of § 452.10(a)(1) (i), (iii), (iv), (vii), and (viii) of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency and pH.

(ii) Samples required: A minimum of five frozen aliquots of each dilution of the concentrated stock solutions, each containing at least 5 milliliters.

(b) *Tests and methods of assay.* The sample solutions must be thawed and brought to room temperature before testing.

(1) *Potency.* Proceed as directed in § 436.105 of this chapter. Prepare the sample for assay by diluting an accurately measured representative portion of the sample with 0.1 *M* potassium phosphate buffer, pH 8.0 (solution 3), to the reference concentration of 1.0 microgram of erythromycin per milliliter (estimated).

(2) *pH.* Proceed as directed in § 436.202 of this chapter, using the solution containing 3,200 micrograms of erythromycin per milliliter.

§ 460.131 Gentamicin concentrated stock solutions for use in antimicrobial susceptibility test panels.

(a) *Requirements for certification*— (1) *Standards of identity, strength, quality, and purity.* Gentamicin concentrated stock solutions for use in preparing susceptibility test panels are frozen aqueous gentamicin sulfate stock solutions serially diluted with distilled water to contain approximately the following concentrations: 640, 320, 160, 80, 40, 20, and 10 micrograms of gentamicin per milliliter. The potency of each diluted solution is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of micrograms of gentamicin that it is represented to contain. The pH of the solution containing 640 micrograms of gentamicin per milliliter is not less than 4.5 and not more than 7.0. The gentamicin used conforms to the standards prescribed by § 444.20(a)(1) (iii), (iv), (v), and (vii) of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain.

(i) Results of tests and assays on the batch for potency and pH.

(ii) Samples required: A minimum of five frozen aliquots of each dilution of the concentrated stock solutions, each containing at least 5 milliliters.

(b) *Tests and methods of assay.* The sample solutions must be thawed and brought to room temperature before testing.

(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion of the sample with 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to the reference concentration of 0.1 microgram of gentamicin per milliliter (estimated).

(2) *pH.* Proceed as directed in § 436.202 of this chapter, using the solution containing 640 micrograms of gentamicin per milliliter.

§ 460.134 Kanamycin concentrated stock solutions for use in antimicrobial susceptibility test panels.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Kanamycin concentrated stock solutions for use in preparing susceptibility test panels are frozen aqueous kanamycin sulfate stock solutions serially diluted with distilled water to contain approximately the following concentrations: 2,560, 1,280, 640, 320, 160, 80, and 40 micrograms of kanamycin per milliliter. The potency of each diluted solution is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of micrograms of kanamycin that it is represented to contain. The pH of the solution containing 2,560 micrograms of kanamycin per milliliter is not less than 6.5 and not more than 8.5. The

kanamycin used conforms to the standards prescribed by § 444.30(a)(1) (i), (iii), (iv), (vi), (vii), and (viii) of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency and pH.

(ii) Samples required: A minimum of five frozen aliquots of each dilution of the concentrated stock solutions, each containing at least 5 milliliters.

(b) *Tests and methods of assay.* The sample solutions must be thawed and brought to room temperature before testing.

(1) *Performance.* Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion with distilled water to the reference concentration of 10 micrograms of kanamycin per milliliter (estimated).

(2) *pH.* Proceed as directed in § 436.202 of this chapter, using the solution containing 2,560 micrograms of kanamycin per milliliter.

§ 460.137 Methicillin concentrated stock solutions for use in antimicrobial susceptibility test panels.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Methicillin concentrated stock solutions for use in preparing susceptibility test panels are frozen aqueous methicillin sodium stock solutions serially diluted with distilled water to contain approximately 6,400, 3,200, 1,600, 800, 400, 200, and 100 micrograms of methicillin per milliliter. The potency of each diluted solution is satisfactory if it is not less than 100 percent and not more than 150 percent for the number of micrograms of methicillin that it is represented to contain. The pH of the solution containing 6,400 micrograms of methicillin per milliliter is not less than 5.0 and not more than 7.5. The methicillin used conforms to the standards prescribed by § 440.36a(a)(1) (i), (v), (vi), (vii), (viii), and (ix) of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Request for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency and pH.

(ii) Samples required: A minimum of five frozen aliquots of each dilution of the concentrated stock solutions, each containing at least 2.5 milliliters.

(b) *Tests and methods of assay.* The sample solutions must be thawed and brought to room temperature before testing.

(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion of the sample with 1.0 percent potassium phosphate buffer, pH 6.0 (solution 1), to the reference concentration of 10 micrograms of methicillin per milliliter (estimated).

(2) *pH.* Proceed as directed in § 436.202 of this chapter, using the solution containing 6,400 micrograms of methicillin per milliliter.

§ 460.140 Penicillin G concentrated stock solutions for use in antimicrobial susceptibility test panels.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin G concentrated stock solutions for use in preparing antimicrobial susceptibility test panels are frozen aqueous penicillin G potassium solutions serially diluted with distilled water to contain approximately 1,600, 800, 400, 200, 100, 50, and 25 micrograms of penicillin G per milliliter. The potency of each diluted solution is satisfactory if it is not less than 100 percent and not more than 150 percent of the number of micrograms of penicillin G that it is represented to contain. The pH of the solution containing 1,600 micrograms of penicillin G per milliliter is not less than 5.0 and not more than 7.5. The penicillin G potassium used conforms to the standards prescribed by § 440.80a(a)(1) (i), (v) and (vi) of this chapter.